SOREDEX

JUL 1 3 2004

510(k) Summary

K040382

Date
February 10, 2004

Submitters Information
Soredex Instrumentarium Corporation
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00510 Helsinki
Finland
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Contact: Kai Lanér

Trade Name
Cranex Basex D or Cranex Excel D

Common Name
Dental panoramic x-ray equipment, digital

Classification
System, X-Ray, Extraoral Source, Digital / MUH

Predicate Device
We consider that Cranex Basex D and Cranex Excel D are substantially equivalent in design, composition and function with Orthophos DS (K983057 & K972312).

Product Description
Cranex Basex D and Cranex Excel D are panoramic extraoral source dental x-ray systems, which produce digital images of dentition. They are modified from the existing Soredex dental panoramic x-ray systems (K880982) by substantially replacing the film image receptor with a digital receptor(CCD). The technique factor settings are constant for the x-ray tube anode voltage (65kV) and current (6 mA DC).

Intended Use
The Cranex Basex D and Cranex Excel D dental panoramic equipments are indicated for dental radiographic examinations by producing digital radiographs of dentition, TM-joints and other oral structures.

Performance data
Verification and validation testing was successfully performed to confirm that Cranex Basex D and Cranex Excel D correspond with the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 3 2004

Mr. Kai Lanér
Soredex Instrumentarium Corporation
Ekimaenkatu 22B
FIN 00510 Heksinki
FINLAND

Re: K040382
Trade/Device Name: Cranex Basex D or Cranex Excel D
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: June 11, 2004
Received: June 14, 2004

Dear Ms. Lanér:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) NUMBER : K040382

DEVICE NAME : Cranex Basex D and Cranex Excel D

INDICATIONS FOR USE :

The Cranex Basex D and Cranex Excel D dental panoramic equipments are indicated for dental radiographic examinations by producing digital radiographs of dentition, TM-joints and other oral structures.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040382